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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

LANDSMAN, ROBERT S

ART UNIT PAPER NUMBER

1647

DATE MAILED: 12/19/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/773,877

Applicant(s)

XIA ET AL.

Examiner

Robert Landsman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/15/02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 31-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) g.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. Formal Matters

- A. The Information Disclosure Statement, filed 9/13/01, has been entered into the record.
- B. Claims 1-37 are pending in the application and were subject to restriction in Paper No. 10 dated 9/3/02. In Paper No.12, filed 10/15/02, Applicants elected Group I, claims 1-30, with traverse. Applicants argue that it would not be a serious burden to search Groups I and II since a search of the literature would be nearly identical since both Groups require a VEGF antagonist. These arguments would be considered, but are not deemed persuasive. "Wound healing" and "psoriasis" are distinct subject matter. A search for "psoriasis" would not necessarily overlap a search for "wounds." Wounds are a much broader category than psoriasis and psoriasis, by one of ordinary skill in the art, would not be considered a wound. Therefore, the restriction is deemed proper and is, therefore, made FINAL.

2. Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

- A. Claims 28 and 29 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims recite "the use of," which is non-statutory language. The claims should be amended to recite, for example, "the method of..."

3. Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- A. Claims 1-30 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the administration of VEGF in an effective amount and the lack of any stated outcome. Though the claims recite, for example, that the intent is to treat psoriasis, there is no recitation of an amount of VEGF to use. The claims simply recite "administering a VEGF antagonist." Similarly, there is no limitation stating that the claimed diseases have been treated, or the severity reduced.

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4. Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

A. Claims 1, 2, 5, 6, 9, 11, 13, 15, 17, 19, 21, 28 and 29 rejected under 35 U.S.C. 102(b) as being anticipated by Kendall et al. (US Patent No. 5,712,380; referenced on the Form PTO-1449 filed 9/13/01). The claims recite a method of treating psoriasis in a mammal, including human comprising administering a VEGF antagonist. The claims also recite reducing the severity of a psoriatic lesion, minimizing the extent of hyperproliferation of keratinocytes associated with psoriasis, reducing or reversing epidermal hyperplasia associated with psoriasis, treating parakeratinosis associated with psoriasis, treating microabcess associated with psoriasis, decreasing reteridges associated with psoriasis. Kendall et al. teach that inhibitors of VEGF (i.e. antagonists) can be used to treat psoriasis (column 1, lines 39-46). Therefore, if psoriasis is treated, it would be inherent in the treatment that the severity, or occurrence, of the other claimed diseases associated with psoriasis would also be treated, or reduced.

Though not being relied upon to make this rejection under 35 USC 102, but simply to show the inherency of the characteristics of psoriasis, Detmar et al. (Introduction; referenced on the Form PTO-1449 filed 9/13/01) teach that epidermal hyperplasia and infiltration of immune cells are characteristic of psoriasis. Similarly, Brown et al. (Introduction; referenced on the Form PTO-1449 filed 9/13/01) teach that epidermal keratinocytes are also a characteristic of psoriasis (Ex parte Novitski, 26 USPQ 1391).

B. Claims 1, 2, 5, 6, 9, 11, 13, 15, 17, 19, 21 and 25-29 rejected under 35 U.S.C. 102(b) as being anticipated by Hu et al. (US Patent No. 6,040,157). The claims recite a method of treating psoriasis in a mammal, including human comprising administering a VEGF antagonist. The claims also recite reducing the severity of a psoriatic lesion, minimizing the extent of hyperproliferation of keratinocytes associated with psoriasis, reducing or reversing epidermal hyperplasia associated with psoriasis, treating parakeratinosis associated with psoriasis, treating microabcess associated with psoriasis, decreasing reteridges associated with psoriasis. Hu et al. teach the use of VEGF antagonistst can be used to treat psoriasis (Abstrsact). Hu et al. also teach the administration of VEGF antagonists by various means, including topical and subcutaneous (column 43, lines 40-45). Therefore, if psoriasis is treated, it would be inherent in the treatment that the severity, or occurrence, of the other claimed diseases associated with psoriasis would also be treated, or reduced.

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Though not being relied upon to make this rejection under 35 USC 102, but simply to show the inherency of the characteristics of psoriasis, Detmar et al. (Introduction; referenced on the Form PTO-1449 filed 9/13/01) teach that epidermal hyperplasia and infiltration of immune cells are characteristic of psoriasis. Similarly, Brown et al. (Introduction; referenced on the Form PTO-1449 filed 9/13/01) teach that epidermal keratinocytes are also a characteristic of psoriasis (Ex parte Novitski, 26 USPQ 1391).

5. Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

A. Claims 3, 4, 7, 8, 10, 12, 14, 16, 18, 20, 22-24 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kendall et al. The claims are identical to those discussed in the rejection under 35 USC 102 except that a specific VEGF antagonist, VEGFR1R2-FcΔC1(a), is used. Furthermore, claims 23 and 24 recite a method of treating inflammatory skin disease and preventing lymphocyte infiltration. The teachings of Kendall et al. are also recited in the above rejection under 35 USC 102. Kendall et al. do not teach the specific antagonist, VEGFR1R2-FcΔC1(a). However, it would have been obvious to one of ordinary skill in the art to have used any antagonist, including VEGFR1R2-FcΔC1(a), to perform the claimed methods, since Kendall et al. teach that antagonists of VEGF, which would include VEGFR1R2-FcΔC1(a), can be used to treat psoriasis. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in substituting the antagonist of the present invention, VEGFR1R2-FcΔC1(a), for the VEGF antagonist of Kendall et al. for the purpose of treating psoriasis.

B. Claims 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kendall et al. in view of Hu et al. (US Patent No. 6,040,157). The teachings of Kendall et al. are recited in the above rejections under 35 USC 102 and 103. Kendall et al. do not teach administering VEGF topically, subcutaneously, or by any other means. However, Hu et al. do teach the administration of VEGF antagonists by various means, including topical and subcutaneous (column 43, lines 40-45). Therefore, it would have been obvious to one of ordinary skill in the art to have administered the VEGF antagonists of Kendall et al. by the routes taught by Hu et al. since both Kendall et al. and Hu et al. teach administration of VEGF antagonists. Furthermore, psoriasis is a topical skin disorder. Therefore, administering the

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antagonists at the site of the disorder (topically) or just below the surface of the skin, but still at the site of the disorder (subcutaneously) would be the most effective and would have the greatest expectation of success.

* Due to the large size of the Hu et al. patent (104 pages), only the pertinent pages have been printed.

6. Conclusion

A. No claim is allowable.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
December 19, 2002

